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The effects of a comprehensive post-treatment recovery program for breast cancer survivors

Keri Ann Hockett

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The Effects of a Comprehensive Post-Treatment Recovery Program for Breast Cancer Survivors

By

Keri Ann Hockett

A dissertation submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy
College of Nursing
University of South Florida

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Keywords: breast cancer, exercise, fatigue, support, uncertainty

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For Stevie

“Follow in my wake
You've not that much at stake
For I have plowed the seas
And smoothed the troubled waters
Come along let's have some fun
The hard work has been done
We'll barrel roll into the sun
Just for starters”

- Jimmy Buffet

Barometer Soup
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ABSTRACT

Background: Breast cancer and its treatment often result in side effects that persist long after treatment has ended. The increased survival rate for breast cancer has allowed for the study of the physical and psychosocial symptoms that persist into the post-treatment period. Although research has tested various interventions and demonstrated improvement in some symptoms, no standard of care exists for management of symptoms in the post-treatment period as part of the continuum of care.

Objective: The aim of this research was to examine the effects of a comprehensive recovery program of education, exercise, and support for breast cancer survivors and to compare the results to a control group.

Method: This experimental study used a convenience sample of 17 women who participated in a structured breast cancer recovery program over a 10-week period, and compared them to a control group of 13 survivors who did not participate in a structured program over a 10-week period. Data were collected on demographic and personal characteristics, extent of disease, and type of treatment. The two subject groups were compared on their self-report responses of physical and social functioning as measured by the SF-36®, their level of distress from fatigue as measured by the Cancer Fatigue Related Distress Scale, and their degree of uncertainty as measured by the Mishel
Uncertainty in Illness Scale. The subjects completed these self-reports at three time points: week 1, week 5, and week 10.

Results: There were no significant demographic differences between the experimental and the control group. Repeated measures ANOVA demonstrated significant differences over time in the experimental group on all measures, except for the physical functioning scale which was approaching significance at p=.06, but no significant differences over time in the control group on any of the measures. Conclusion: The Return to Wellness program was effective in improving social functioning and vitality in women with breast cancer who completed the program. It was also effective in reducing uncertainty and distress associated with cancer related fatigue.
Chapter One

Introduction

Breast cancer is the most commonly occurring cancer in women in the United States. Approximately 200,000 women are diagnosed with breast cancer annually (2005). Advances in screening, early detection, and newer treatments have led to an increased overall five-year survival rate that approaches 87%, and is much higher for early stage, localized disease (National Cancer Institute, 2003). These advances in breast cancer treatment mean that many more women are alive today than ever before due to the increased survival rate. As more and more women are cured of their disease, the number of breast cancer survivors in the general population continues to climb, and thus we learn more about the long-term sequelae of treatment and the issues of survivorship.

The current standard of care for the treatment of breast cancer can include any combination of surgery, chemotherapy, radiation therapy, biotherapy, hormonal therapy, and most recently, targeted therapies with monoclonal antibodies. The type of treatment prescribed depends on the stage of the disease, the histological characteristics, and the presence or absence of hormonal receptors and growth receptors. The physical condition of the woman and her menopausal status also is considered. Each treatment has its own unique set of side effects and potential complications that often require additional therapies to manage them. When combined, these treatments may act synergistically to eradicate the cancer cells, but at the same time they may serve to intensify adverse side effects and symptoms. There may also be differences in symptom burden among age
groups and by type of treatment (Cimprich, 1992; Greene, Nail, Fieler, Dudgeon, & Jones, 1994). Findings indicate that as women complete their physical treatments, they experience side effects that linger long after treatment has ended (Jacobsen et al., 1999). The most commonly experienced physical and psychological symptoms are fatigue, pain, sleep disturbances, weight gain, anxiety, cognitive impairment, depression, and uncertainty about cancer recurrence and death (Jacobsen et al., 1999; Mishel, Padilla, Grant, & Sorensen, 1991). In addition, breast cancer patients have described an altered sense of femininity, and decreased physical attractiveness. Moreover, the side effect of lymphedema may develop and continue beyond the treatment period (Brady et al., 1997). Fatigue is consistently identified in the literature as the symptom most bothersome to breast cancer patients and is the one of longest duration (Jacobsen et al., 1999; Longman, Braden, & Mishel, 1997). The persistence of any one of these symptoms can significantly prolong a less than optimal level of functioning for these women. These symptoms and their associated problems can continue months to years after the completion of treatment, effectively altering patterns of adjustment and adaptation, and therefore inhibiting the return to optimal functioning and well being (Spiegel, 1997). Decreased social and physical levels of functioning can have profound economic implications, resulting in the inability to return to work or to perform prior social roles and responsibilities adequately. Upper-body limitations, advanced disease, and working in jobs requiring manual physical activity have been associated with the need for longer medical leave time (Satiriano & DeLorenze, 1996). In addition, systemic chemotherapy as part of past treatment has been found to be a predictor of poorer quality of life in long term survivors of breast cancer (Ganz et al., 2002).
The role of psychosocial support has demonstrated positive results in facilitating adjustment and adaptation during and after treatment for cancer. Support groups have been instrumental in improving psychosocial functional levels for breast cancer survivors. Upon completion of treatment, many women have expressed a sense of abandonment coinciding with no longer visiting the clinic or the physician (Dow, Ferrell, Haberman, & Eaton, 1999). Concerns about cancer recurrence do not necessarily diminish with length of time out from diagnosis or completion of treatment (Holzner et al., 2001; Polinsky, 1994). The types of support groups studied have included open-ended support groups, self-help groups, and educational or cognitive-behavioral interventions. All these types of support groups have been shown to improve coping abilities, mastery, and to decrease stress, promote hope, improve quality of life, and decrease symptom distress, including distress from fatigue and uncertainty (Burish & Tope, 1992; Cella & Yellen, 1993; Enbright & Lyon, 2002; Fobair, 1997; Ream & Richardson, 1999). Cimprich (1999) found identifiable patterns of symptom distress in women with breast cancer prior to beginning treatment, suggesting the need to begin interventions toward adjustment much sooner.

The role of physical rehabilitation in overcoming the physical deconditioning that occurs specifically among breast cancer survivors has only been explored over the last decade. The recent surge in the number of physical rehabilitation programs aimed at breast cancer survivors coincides with the advances in treatment and the increased survival rate. Published studies report that such interventions improve overall physical functional capacity, enhance quality of life, and reduce levels of fatigue (Mock et al., 1997; Schwartz, 2000b; Winningham, MacVicar, Bondoc, Anderson, & Minton, 1989).
The form of physical rehabilitation used most often for this purpose is an exercise-based program.

Research has not been consistent regarding the initiation of exercise programs, therefore, the place for a formal post-treatment exercise or rehabilitation program as part of the continuum of breast cancer care and recovery is yet to be defined. While pulmonary rehabilitation programs, lymphedema programs, and general physical rehabilitation programs exist for facilitating adaptation to specific physical alterations, no clear published evidence exists regarding defined treatment parameters for assisting women in adapting to the physical and psychosocial issues of breast cancer survivorship. It is now known that breast cancer treatment often leads to weight gain, and studies have revealed that an increased body mass index is associated with an increase in breast cancer recurrence and increased mortality rate from the disease (Brown et al., 2003). This suggests a need to investigate ways to minimize or reverse weight gain from breast cancer treatment. Physical rehabilitation efforts, however, can be limited by anemia and low platelet counts which increase risk for bleeding, nausea, and pain (Beck, 2003). Severe peripheral neuropathies which can interfere with balance, and osteoporosis as a result of treatments that induce menopause and decrease bone mineral density may also inhibit physical interventions (Swenson, 2005; Wampler, 2005).

The Return to Wellness program is a 10-week program of physical exercise, education, and psychosocial support designed to help women adjust to survivorship. It was developed by The Wellness Community, a national not-for-profit organization dedicated to improving the quality of life in cancer survivors through psychosocial support and education. The Wellness Community serves only people affected by cancer
as well as their significant others. All support groups at The Wellness Community are facilitated by professionals, most of whom are licensed clinical psychologists, licensed clinical social workers, and licensed mental health counselors. All services are provided free of charge. There are more than 20 separate centers of The Wellness Community throughout the United States. The Wellness Community operates under the “Patient Active” concept, which stresses that, through support and education, patients and their significant others can be empowered to actively take part in their treatment and recovery. The Wellness Community believes that active patient participation in treatment and recovery reduces emotional and psychological distress, particularly aloneness, loss of control, and loss of hope. The Wellness Community offers support, education and other programs such as Return to Wellness as a way to reduce these stressors. (J. Kleinbaum, personal communication, March 5, 2004). The Wellness Community partners with other local community agencies in its area, such as hospitals, to offer the physical exercise portion of the Return to Wellness program.

**Problem Statement**

The first Return to Wellness program was a partnership between The Wellness Community San Francisco and a hospital in southern California. The Return to Wellness training manual states that the purpose of Return to Wellness is to help “women with breast cancer acquire important information and support for life after treatment so that they may recover from the physical and emotional effects of breast cancer treatment more fully and more quickly” (page 2). No formal goals or objectives have been written from which to develop the program, and no evaluative data have been published. An unpublished report on the Return to Wellness pilot program does state that there were
small but significant reductions in mild to moderate depression on the Geriatric Depression Scale. Also reported were small reductions in body fat, small weight losses, and small improvements in strength, flexibility, endurance, and cardiovascular fitness. No statistical or demographic information is provided to substantiate this information. Other than naming the Geriatric Depression Scale, no instruments or methods are described for measuring the reported outcomes from the pilot program (Kraemer, 2001).

The purpose of this study is to measure the effects of the Return to Wellness program, a structured program of physical exercise, education, and psychosocial support, on women who have completed treatment for breast cancer.

_Hypotheses_

The hypotheses to be tested in this study are:

Women treated for breast cancer who complete the Return to Wellness program will:

1. report significantly improved physical functioning, social functioning and vitality compared to a control group as reported on PF, SF and VT scales of the SF-36.
2. have significantly lower scores on the Mishel Uncertainty in Illness Scale (MUIS) compared to a control group.
3. report significantly less distress from fatigue on the Cancer Related Fatigue Distress Scale (CRFDS) compared to a control group.

_Definition of Terms_

For the purpose of this study, the following terms are defined:

Uncertainty - according to Mishel and Braden, (1987), uncertainty is a cognitive state that occurs when a person cannot assign meaning or structure to a particular situation because cues are not present. For breast cancer survivors, the actual outcome is not known for
certain, and information may be lacking regarding cure, recurrence, and prognoses for various side effects and conditions. Uncertainty also can be linked to a lack of social support, a lack of education, or a lack of a credible authority. Credible authority means trust and confidence in one’s health care provider.

Cancer-related fatigue distress- cancer related fatigue is defined by the National Comprehensive Cancer Network (NCCN) as “a persistent, subjective sense of tiredness related to cancer or cancer treatment that interferes with usual functioning” (Mock et al., 2000). It is a multidimensional, subjective symptom that has physiological, emotional, psychological and spiritual aspects. It is prevalent in up to 100% of patients who receive chemotherapy and in up to 93% in patients who are treated with radiation therapy. It remains a bothersome symptom in up to 40% of cancer survivors (Broeckel, Jacobsen, Horton, Balducci, & Lyman, 1998; Ream & Richardson, 1999). According to Holley (2000b), cancer related fatigue distress is the suffering that is a consequence of cancer related fatigue.

Deconditioning- many of the self-care strategies that patients use to alleviate or minimize fatigue actually worsen the fatigue. The most common practice among patients is to rest, nap, or sleep more (Richardson & Ream, 1997). This actually contributes to further physical deconditioning. Physical deconditioning is defined as the process whereby the body’s ability to perform work is decreased in response to less and less demand over a period of time. The body therefore adjusts to a decreased level of functioning (Winningham, 1996).
Significance to Nursing

Currently there are no evidence-based guidelines for nursing regarding the standard for education, intervention and evaluation for the woman recovering from a breast cancer diagnosis upon completion of treatment. Evidence-based clinical research can assist in identifying the interventions most likely to be successful in assisting women to adjust effectively to survivorship, and achieve optimal physical and psychosocial functioning after a breast cancer diagnosis and treatment. This research is a beginning step toward that process. The information gained from this study may generate new knowledge that nurses and other health care providers can use to better articulate the role of structured rehabilitation programs. It also may help to define program content and format, and formulate expected outcomes for the woman recovering from breast cancer, and may demonstrate that the continuum of care extends beyond completion of the prescribed treatment period.

Summary

Chapter one discusses the physical and psychosocial implications of a breast cancer diagnosis and treatment, and how these effects linger well into the post-treatment phase of survivorship. No formal evidence-based guidelines exist to define the standard of care for women in this transition, and the currently defined continuum of care does not adequately extend beyond the conventional treatment phase. An exploratory research study is proposed to determine if an existing structured program of exercise, education and support will be effective in improving physical and social functioning, lessen feelings of uncertainty, and relieve distress from fatigue associated with cancer treatment.
Chapter Two

Review of the Literature

This chapter presents a synthesis of the literature related to the concepts of uncertainty and fatigue related distress, as well as self-help interventions to improve physical and social functioning that were tested with breast cancer survivors. In addition, studies related to education, support, and physical interventions such as exercise and yoga with breast cancer survivors are reviewed. An electronic search of four databases (Medline, Proquest, Ovid, and CINAHL) was conducted to identify the pertinent literature printed in English and published from January 1993 to May 2005. Keywords for the search were: breast cancer, rehabilitation, survivorship, fatigue, uncertainty, psychosocial, distress, exercise, recovery, support, education, yoga, complementary, and integrative. The searches using these keywords produced 173 articles. Additional studies were located through ancestry search of previously acquired articles and reports.

In 2004, the Institute of Medicine and the National Research Council produced a report called Meeting the Psychosocial Needs of Women with Breast Cancer (2004). This report estimates that approximately one-third of all breast cancer patients experience psychosocial distress, and that risk factors associated with distress are younger age, pre-existing mental illness, physical comorbidities, sexual difficulties, and lack of social support.
Uncertainty

Uncertainty is a cognitive state that occurs when a person is unable to assign meaning or structure to an event (Mishel & Braden, 1987). Upon completion of treatment, many women with breast cancer experience a heightened sense of uncertainty related to no longer needing regimented care in the form of frequent visits to their physician and clinic staff. The completion of treatment can signify the transfer of their care back to their primary care physician and the loss of regular reassurance from their cancer care providers (Institute of Medicine & National Research Council, 2004). According to McCormick, (2002) one of the problems in defining and describing uncertainty is the inability to separate it as an isolated concept from the situation-associated emotions that provoke it. The completion of breast cancer treatment can leave women with a sense of foreboding about their future. This degree of uncertainty is further compounded by the fear of recurrence (Holland & Rowland, 1991). Ill-prepared to deal with the lingering physical and psychosocial effects of the disease and/or its treatment, breast cancer survivors entering the post-treatment phase often find themselves questioning the meaning of their symptoms and the validity of their level of concern (Rowland & Massie, 1998).

Mishel (1990) has theorized that uncertainty in chronic illness is mediated by social support, education, and credible authority. Numerous studies have been undertaken to test these concepts for their utility as effective mediators in facilitating psychosocial adjustment. In particular, the impact of social support in reducing distress has been studied extensively. Social support consists of both emotional support and instrumental support (Finfgeld-Connett, 2005). Emotional support involves comforting
and consoling a person in order to reduce uncertainty, anxiety, and stress (Jankowski, Videka-Sherman, & Laquidara-Dickinson, 1996; Sandstrom, 1996). Emotional support does not have to involve a physical presence on the part of the support person, but rather can exist in the form of cards and letters, telephone calls and more recently, through the internet (Gurowka & Lightman, 1996; Prudhoe & Peters, 1995; Tichon & Shapiro, 2003). Instrumental support involves providing goods and services such as transportation, food, housekeeping and physical care (Finfgeld-Connett, 2005; Gilliland, 2001; Gurowka & Lightman, 1996). According to Finfgeld-Connett, (2005), patients prefer that social support come from non-professionals.

Dirksen (2000) conducted a study that demonstrated social support to be the strongest predictor of higher self-esteem and well-being in breast cancer survivors, while uncertainty was found to be a negative predictor of resourcefulness. Similar results were found in a study of younger breast cancer survivors by Sammarco (2001) where study findings supported the positive relationship between social support and quality of life, and a negative correlation between uncertainty and social support, and also between uncertainty and quality of life in breast cancer survivors under age 50. The results also demonstrated a positive relationship between social support and the size of the support network.

The majority of studies that examine prevalence and mediators of distress in breast cancer survivors are cross-sectional and/or focus only on the initial post-treatment period (Helgeson, Snyder, & Seltman, 2004). There are however, a handful of studies that examine distress in breast cancer patients at more than one point in time, or further beyond the immediate post-treatment period. One such study of survivors five to nine
years post-treatment identified triggers of uncertainty as hearing about some else’s cancer and having new aches and pains (Gill et al., 2004). In examining characteristics of risk for psychological distress in breast cancer survivors at one year post diagnosis, Schag et al. (1993) found that high risk for psychological distress was based upon a history of depression, significant physical or psychological stressors prior to or during diagnosis and treatment, or having serious economic, vocational or marital problems.

In a study of survivors at three months and 12 months after surgery for breast cancer, it was found that social support becomes critical later in the post-operative period, and that the need for social support continues as the time out from surgery increases (Enbright & Lyon, 2002). In a study of couples, breast cancer patients and their partners completed four inventories at six different time periods from the immediate post-surgical period to one year. Emotional adjustment was predicted by marital support, other social support, and role function, while social role functioning was predictive of physical adjustment (Hoskins et al., 1996).

The Self-Help Intervention Project was a large study conducted by Longman, Braden, and Mishel to test three interventions consisting of a self-help course, uncertainty management, or a self-help course plus uncertainty management. All three interventions were shown to be effective in increasing self care and psychological adjustment, especially in women who demonstrated low resourcefulness (Braden, Mishel, & Longman, 1998; Longman, Braden, & Mishel, 1996; Longman et al., 1997; Longman, Braden, & Mishel, 1999).

The role of education in the form of videotape, telephone counseling or education with telephone counseling has demonstrated significant improvement in physical,
emotional, and social adjustment (Longman et al., 1997, 1999). The effectiveness of educational audiotapes was further found to increase self-care behaviors in women undergoing treatment for breast cancer (Williams & Schreier, 2004). Similar results were found by Lev and Owen (2000) in a study of a counseling intervention consisting of videotape, booklet and trained nurse counselor sessions at regular intervals. Findings suggested that the interventions were useful for improving quality of life and reducing distress.

Exercise and Physical Activity

In the last decade, there has been a surge in the amount of research examining the role of physical activity in the primary prevention of breast cancer as well as the prevention of recurrence. Since the mid-1990s, studies have shown modest reduction in the initial incidence of breast cancer in women who engage in a higher level of physical activity (McTiernan, 2000; Patel, Callel, Bernstein, Wu, & Thun, 2003; Pritchard, 2004). More recently, there has been an increased focus on the role of physical activity and exercise in extending survival and reducing the rate of recurrence after a breast cancer diagnosis (Enger & Bernstein, 2004; Holmes, 2005). In addition, the role of physical activity has been studied to determine when and how often it is used to test for its effects on quality of life, physical functioning, fatigue, and symptom burden in both short and long term survivors, and in women who are still under treatment. Because the effects of physical exercise take time to become evident, most studies of the effects of exercise interventions in breast cancer survivors are longitudinal, and employ both observational as well as interventional study designs.
The national Centers for Disease Control and Prevention (CDC) has established recommendations for physical activity for American adults. These recommendations state that adults should engage in moderate physical activity for at least 30 minutes for a minimum of five times per week. Alternately, if engaging in vigorous physical activity, then 20 minutes or more at least three times per week is recommended (Department of Health and Human Services Centers for Disease Control and Prevention/American College of Sports Medicine, 2005). Few researchers, however, utilize or incorporate this operationalized definition into the method of their studies.

One of the exercise strategies used in the Return to Wellness Program is physical conditioning through strength training with resistance bands. Strength training with either bands or free weights has been shown to be effective in increasing bone mineral density and strength, reducing body fat, increasing muscle-to-fat ratio, and boosting metabolism (Galvao & Newton, 2005; Kasper, 2004). According to the CDC (2005), strength training also has been found to improve balance, reduce risk of falls, improve glucose control, help maintain body weight, and improve the quality of sleep. The other exercise method employed in the Return to Wellness program is yoga. Yoga has been shown to improve physical functioning and social well-being while also decreasing fatigue in breast cancer survivors undergoing treatment (Moadel, 2003). It also has been shown to improve overall quality of life, decrease symptom distress, and enhance immune function (Carlson, Speca, Patel, & Goodey, 2003). It should be noted that there are many anecdotal references to the use of yoga as a complementary therapy in many cancers, but very little rigorous scientific evidence is currently published. This is a
relatively new area of research in the western hemisphere. Scientific studies that are published demonstrate that yoga has been useful in improving aerobic capacity in healthy adults and those with asthma, and mood improvement in healthy adult students (Manocha, 2003; Netz & Lidor, 2003; Ray et al., 2001). Both yoga and strength training are considered to be forms of moderate physical activity by both the CDC and the American College of Sports Medicine (Department of Health and Human Services Centers for Disease Control and Prevention/American College of Sports Medicine, 2005).

A longitudinal study of exercise behaviors in breast cancer survivors found that those women who did participate in exercise did not increase the amount of their exercise over time, and at all measurement time points all of the women were exercising below the recommended level of minutes of exercise. Among those who did exercise, there was a reported increase in physical functioning, but no improvement in mood or symptoms (Irwin et al., 2004; Pinto, Maruyama et al., 2002). Similar results were found in a study by Blanchard et al. (2003) that demonstrated breast cancer survivors engage in as much exercise as controls, though they participate in different activities than controls, but still below the government recommendations. In a long-term study of breast cancer survivors who were on average, eight years post-surgery, it was found that, compared to baseline measures, decreases in physical and social functioning persist well past the initial post-treatment phase (Polinsky, 1994). These findings were supported by a study of upper-body strength in breast cancer survivors that revealed self-reported upper-body functional limitations are greater than age-matched controls and persist well into the post-treatment period. At one year, the greatest improvement was seen in the youngest age groups (Satiriano & Ragland, 1996). Even with such evidence, the literature has yet to yield any
rigorous studies that examine the prevalence and effects of a sustained, long-term program of exercise.

It is important to understand the factors affecting a breast cancer survivor’s motivation to exercise and willingness to adhere to an exercise program. One such factor is physician support (Knols, Aaronson, Uebelhart, Fransen, & Aufdemkampe, 2005). Breast cancer patients initiate exercise significantly more when their oncologist has recommended they exercise (Jones, Courneya, Fairey, & Mackey, 2004). Other determinants of initiation and adherence include intention, extraversion, support from significant others, perceived control, exercise preferences and past exercise history, level of fatigue, co-morbidities, and younger age (Courneya, 2003; Courneya, Blanchard, & Laing, 2001; Pinto, Trunzo, Reiss, & Shiu, 2002; Rhodes, Courneya, & Bobick, 2001). Similar findings were supported in study by Rogers (2004) that also supported time management and social networking as determinants of initial motivation to exercise.

In randomized controlled trials of breast cancer patients that compare supervised exercise to control groups of standard care and/or self-directed exercise, results have been mixed. Segal et al (2001) demonstrated significantly higher improvement on the physical function scale of the SF-36 in subjects that practiced self-directed exercise over those in a supervised exercise program, but no demonstrable effect on quality of life. Alternatively, Courneya (2003) demonstrated significantly higher improvements in both quality of life and cardiopulmonary function in a supervised exercise group of post-menopausal breast cancer survivors. Similar results were found in non-randomized controlled studies that employed supervised group exercise therapy (GET) (Kolden et al., 2002). Structured exercise programs also have been found to
improve exercise tolerance, sleep quality, and quality of life, and help control body weight (Schwartz, 2000b; Winningham et al., 1989; Young-McCaughan et al., 2003). Additional studies of structured exercise programs in cancer survivors have demonstrated decreased levels of depression and anxiety, less psychological distress, and improved overall mood among those who exercise (Campbell, Mutrie, White, McGuire, & Kearney, 2005; Carter, Drum, Hayward, & Schneider, 2003; Pinto, Clark, Maruyama, & Feder, 2003; Schulz et al., 1998).

**Exercise and Fatigue**

Research studies have shown that fatigue level or intensity of fatigue is related to type of treatment, and in breast cancer patients it is particularly associated with treatment that involves chemotherapy (Donovan et al., 2004; Woo, Dibble, Piper, Keating, & Weiss, 1998). Fatigue has also been found to be associated with a number of other symptoms, existing as a symptom cluster, and these clusters serve to intensify the effect of the individual symptom (Bender, Ergyn, Rosenzweig, Cohen, & Sereika, 2005; Berger, 2005). Research has also demonstrated that fatigue lasts well into the post-treatment period and is more intense than normal fatigue and causes more suffering (Holley, 2000a; Sugawara et al., 2005)

Only two strategies for fatigue management have had sufficient research to qualify as evidence-based recommendations: management of anemia, and exercise programs (Barsevick, Whitmer, Sweeney, & Nail, 2002). A number of studies not only examine the effect of a program of exercise on physical functioning and quality of life, but also test improvement in fatigue level as an endpoint. The use of exercise and sleep have been shown to be the most effective strategies used by patients themselves to lessen
the effects of fatigue (Graydon, Bubela, Irvine, & Vincent, 1995). Mock et al. (1994) found that an exercise program of walking combined with a support group not only improved physical functioning, but lessened the intensity of 12 symptoms, including fatigue and anxiety. In a later study, Mock et al (1997) tested the effectiveness of a home-based exercise intervention that consisted of a self-paced walking program that yielded similar results. This was later supported in a randomized control trial demonstrating that a home based walking program is an effective mediator of fatigue (Mock et al., 2005). Additional studies of home-based exercise programs involving walking support this intervention as effective in decreasing fatigue, increasing physical functioning and improved quality of life (Schwartz, 1999, 2000a; Schwartz, Mori, Gao, Nail, & King, 2001).

Educational instruction has been tested for effectiveness in managing fatigue levels. An eight week program of education and support that included exercise instruction and energy conservation instruction demonstrated significant differences between pre-to post measures for fatigue and quality of life in patients with cancer (Holley & Borger, 2001). These results were supported by a pilot study demonstrating that a large scale fatigue management program consisting of telephone education for energy conservation and management of activity is useful in reducing fatigue (Barsevick et al., 2002).

**Conceptual Framework**

The guiding conceptual framework for this study is based on the Patient Active® concept of The Wellness Community. This concept was developed by The Wellness Community founder, Harold Benjamin, a social psychologist. The Patient Active® concept posits that
patients who actively participate in their cancer treatment and fight for recovery may actually enhance their recovery (Benjamin, 1987).

A cancer diagnosis usually imposes a certain degree of loss of personal control. A patient becomes entrenched in appointments for work-ups such as blood work and multiple imaging studies, treatments such as weekly chemotherapy that are sometimes followed by daily injections to prevent infection, and periods of frustration waiting for test results and other information. Physical side effects of treatments can further victimize a patient by limiting their normal activities of daily living. The Return to Wellness program provides psychosocial support and education from credible authorities, such as physicians, nurses, licensed mental health counselors, psychologists, dieticians, and survivors in order to empower women towards healthy psychological adjustment and maintaining a sense of personal control. It also teaches physical self-help strategies to manage fatigue, loss of strength, and loss of flexibility, thus enabling women to actively facilitate their recovery from breast cancer (Figure 1).

**Figure 1.** Conceptual Model
Summary

Chapter two has established that breast cancer survivors experience symptoms of psychosocial distress in the form of uncertainty and that social support and education from credible authorities are effective in facilitating adjustment. Breast cancer survivors also experience extended levels of fatigue and decreased physical functioning that continues long into the post-treatment phase of survivorship. Physical exercise has been shown to improve physical functioning, elevate mood, and reduce levels of fatigue in breast cancer survivors who participate in structured or home-based exercise programs. Programs that combine interventions have also been successful in demonstrating improvement of symptoms. It is important to test the efficacy of a combined program of physical activity, education and social support in improving health outcomes.
Chapter Three

Method

Research Design

The purpose of this study was to measure the effects of the Return to Wellness program, a 10-week program of supervised physical exercise, education, and psychosocial support on physical functioning, uncertainty and distress from fatigue. This study employed a two-group repeated measures comparative design. This chapter describes the study design and method.

Sample and Setting

Subjects for the experimental group were recruited from those women who registered for the Return to Wellness program. To participate in the Return to Wellness program, a woman must have had a diagnosis of breast cancer and have completed her treatment in the last three weeks to two years. She must not have had any known active cancer disease. Each Return to Wellness participant signed a consent form to participate prior to beginning the program (Appendix A). The women were told that they must have approval from their physicians, and their physicians either signed the patient consent form or wrote an approval on a prescription slip or practice letterhead. Prior to the program, medical history, exercise history and nutritional history forms were completed (Appendix B).

The 20 sessions of the Return to Wellness program consisted of two sessions per week for 10 weeks. Each session was two hours long, and all sessions were delivered in
a group setting. A sample program schedule is included in Appendix C. Each week, the participant received strength and conditioning instruction from a physical therapist in the form of weight training or resistance training with TheraBand activity, which are elastic bands in varying degrees of resistance. The bands can be used to work many different muscle groups by causing two different types of contraction.

Each participant in the Return to Wellness program was screened by the physical therapist for the presence of lymphedema in the affected arm(s). The physical training sessions lasted approximately one hour and were preceded by a one hour support group. The second session of the same week involved a one hour educational session that was mainly focused on managing physical or psychological symptoms such as fatigue through energy conservation; eating properly, managing feelings, and dealing with insurance issues. The educational session was followed by a one hour yoga session taught by a certified yoga instructor. The yoga was focused on breathing exercises and meditation. It was mainly seated yoga and involved minimal mat work. At the end of the 10 week program a graduation was held.

Control subjects were recruited from two large private oncology clinics and an area hospital clinic. Potential subjects were referred to the investigator by health care providers at these facilities. Subjects contacted the investigator for information about the study. Control subjects had to meet the eligibility criteria for the Return to Wellness program; that is, they must have completed treatment in the last three weeks to two years and have had no evidence of cancer disease. Control subjects did not require physician permission as they were not participating in an intervention, and there were no known risks to filling out health surveys and questionnaires. Exclusion criteria was the same as
the Return to Wellness program, that is, evidence of disease; or pre-existing cardiac
disease. All Return to Wellness sessions and interventions took place either in an
outpatient satellite campus of a large community hospital, or at The Wellness Community.

Instruments

Medical Outcomes Study Short Form-36

Improvements in physical and social functioning and vitality were measured by
changes in the pre- to midpoint to post- scores of the physical functioning, social
functioning, and vitality scales of the Medical Outcomes Study Short Form- 36 (SF-36)
(Appendix D). The SF-36 Health Survey is a self-administered 36-item scale with eight
scales that purport to measure functional health and well-being. The eight scales are
physical functioning, role-physical, bodily pain, general health, vitality, social functioning,
role-emotional, and mental health. Each item has a five choice, Likert-type response
check box. A higher score on the scale indicates a higher degree of functioning in the area
it purports to measure. The eight scales yield two summary measures, four of the scales
yield a physical summary measure and the other four comprise a mental health summary
measure (Ware, Snow, & Kosinski, 2000).

Scoring the SF-36. Each scale of the SF-36 yields a separate score. A higher
score on the individual scale indicates a better health state. Ten items on the SF-36 require
recoding. After recoding, raw scale scores were transformed in new scale scores.
Transformation was not required unless making comparison to existing data.

Validity and reliability. The SF-36 has been used extensively and evidence for
content, criterion, construct and predictive validity have been shown. Content validity was
assessed by comparing the SF-36 to ten other survey forms. Factor analysis supported construct validity, and correlational studies support criterion validity. Reliability estimates were made using both internal consistency and test-retest methods. Reliability estimates for the instrument range from .70 to .93 with the majority of studies above .80 (Ware et al., 2000) (Appendix D).

*Cancer Related Fatigue Distress Scale*

Distress related to cancer fatigue was measured by the Cancer Related Fatigue Distress Scale (CRFDS) (Holley, 2000a). The CRFDS is a 20 item ratio-level grading scale. Each item is graded on a zero to ten scale. The CRFDS has 20 items that are scored on a zero to 10 numeric rating scale. A higher score on the scale indicates a higher degree of distress related to fatigue. No recoding or transformation of scores is required. Total scores for this instrument can range from zero to 200. (Appendix D)

*Validity and reliability.* Content validity was assessed by means of a content validity index (CVI) using cancer survivors as expert judges. The reported mean content validity index was .91. Construct validity was supported by factor analysis with items loading on a single factor solution. Reliability estimates for internal consistency from the CRFDS instrument development study demonstrated a Cronbach’s alpha coefficient of .97.

*Mishel Uncertainty in Illness Scale*

Uncertainty was measured by the Mishel Uncertainty in Illness Scale-Community Form (MUIS-C), a 23-item scale that measures uncertainty that is perceived in illness developed by Dr. Merle Mishel (1981). The scale has four subscales which are ambiguity, unpredictability, complexity, and inconsistency of information. Only the total score for this instrument was used in this study. Each item is scored on a five-point, Likert-type
scale. Higher scores on the MUIS-C indicate a higher degree of uncertainty. Total scores can range from 23-115.

*Validity and reliability.* Construct validity for the MUIS-C has been supported through factor analysis. According to Mishel and Braden (1987), reliability estimates for internal consistency of the MUIS demonstrate alpha coefficients of greater than .92. The MUIS-C has been used extensively in studies of breast cancer survivors (Longman et al., 1997, 1999).

**Procedures**

*Approvals*

A letter indicating support for the study was obtained from The Wellness Community. Support letters were also secured from the two local oncology clinics. Approval for this study was received from the University of South Florida Institutional Review Board for Human Subjects Protection, as well as the Sarasota Memorial Hospital Institutional Review Board. In order not to burden subjects with two consent forms, the Sarasota Memorial Hospital IRB agreed to waive their informed consent form in favor of the University of South Florida IRB consent form (Appendix E).

*Intervention*

Subjects were contacted and recruited by an “invitation to participate” letter handed out at the time of registration for the Return to Wellness program (Appendix F). Potential subjects for matched controls were invited to participate by letter to those on the waiting list for the Return to Wellness program, and by invitational letters or by a personal invitation to participate to patients identified by clinic physicians and staff as a patient who has completed treatment. For those who expressed interest in participating in
the study, the investigator explained the study and answered any questions. Signatures on the informed consent were obtained by the investigator, and the study participants were given a copy of their consent form to keep.

Data Collection

For study participants who were enrolled in the Return to Wellness program, data collection with the SF-36, CRFDS, and MUIS-C occurred immediately prior to the first session, again prior to the 5th session, and again immediately after the end of the 10-week session. For participants who were matched controls, data collection began at the time of informed consent. Surveys were mailed at time of consent, mailed again five weeks later, and again at approximately 10 weeks after the date on the first survey. Participants who did not return their forms were called to determine whether they wanted to continue in the study.

Data Analysis

The Statistical Package for the Social Sciences (SPSS) (version 13.0) was used for all data analysis and data management. A two-way repeated measures ANOVA with between-groups design was employed. A priori power analysis had determined that 45 subjects per group were needed for a medium effect at an alpha level of .05 and a correlation of .05 for a design with three measures. However, the Return to Wellness program was affected by dwindling interest in the program and lack of funding to continue. After three 10-week programs over the period of one year, only 19 subjects had agreed to participate. Two of those subjects did not complete the program and their data could not be included as they only took the pre-test measures. Similar lack of interest occurred in getting health care providers to recommend the study to women with
breast cancer who finished treatment. After a one year period, only 16 women agreed to participate and three of those women decided not to complete the study, citing personal reasons.

Data are presented descriptively as percentages for categorical variables and as means and percentages for continuous variables. The data analysis plan is presented below with each hypothesis. The hypotheses in this study were as follows:

Women treated for breast cancer who complete the Return to Wellness program will:

1. report significantly improved physical functioning, social functioning and vitality compared to a control group as reported on PF, SF and VT scales of the SF-36. After recoding and scoring, these three scale variables were analyzed for means and standard deviations by time and by group. Repeated measures ANOVA was employed to analyze the main effects of time, the main effects of group, and the interaction effect of time by group.

2. have significantly lower scores on the Mishel Uncertainty in Illness Scale (MUIS) compared to a control group. After scoring, the total instrument scores were analyzed for means and standard deviations by time and by group. The subscales of this instrument were not analyzed. Repeated measures ANOVA was used to analyze the main effects of time, the main effects of group, and the interaction effect of time by group.

3. report significantly less distress from fatigue on the Cancer Related Fatigue Distress Scale (CRFDS) compared to a control group. After scoring, the total instrument scores were analyzed for means and standard deviations by time and
by group. Repeated measures ANOVA was used to analyze the main effects of
time, the main effects of group, and the interaction effect of time by group.
In addition, a chi-square test was performed to look for significant differences in the
demographic profiles of the two subject groups, and an independent samples t-test was
carried out to look for significant difference in mean age between the two groups.
Chapter Four

Results

Chapter four presents the study results. Results are organized as follows: profile of the study groups and an analysis of each study aim.

Profile of Samples

Experimental group

A convenience sample of 17 breast cancer survivors who enrolled in the Return to Wellness program were recruited to participate in the study. Descriptive statistics were performed on demographic and clinical information. One subject did not provide information on lymph node involvement and consequently that variable is based on a sample size of 16. The median and mean age of the subjects in this group was approximately 55 and 56 years respectively. There was a wide range in age of subjects within this study sample, with the youngest being 38 years of age and the oldest being 75 years of age. The most common age was 51 years (three subjects) followed by 66 years (two subjects).

As depicted in Table 1, the sample was primarily Caucasian, and with an average of 14 years of education. One hundred percent of the sample had surgery, 65% being in the form of lumpectomy and the other 35% having mastectomies. All of the women in
this sample reported having participated in a support group and 65% reported currently performing some type of exercise.

### Table 1

**Sample Composition**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>17</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>16</td>
</tr>
<tr>
<td>African American</td>
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<tr>
<td>Hispanic</td>
<td>1</td>
</tr>
<tr>
<td><strong>Type of Surgery</strong></td>
<td></td>
</tr>
<tr>
<td>Lumpectomy</td>
<td>11</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>6</td>
</tr>
<tr>
<td><strong>Lymph node involvement</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>8</td>
</tr>
<tr>
<td>Local</td>
<td>5</td>
</tr>
<tr>
<td>Regional</td>
<td>2</td>
</tr>
<tr>
<td>Don’t know</td>
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<tr>
<td><strong>Treatment Modality</strong></td>
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<td>Surgery</td>
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<td>Chemotherapy</td>
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<tr>
<td>Radiation Therapy</td>
<td>11</td>
</tr>
<tr>
<td>Hormone Therapy</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
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</tr>
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<td>Experienced Lymphedema</td>
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<td>Currently Exercise</td>
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</tr>
<tr>
<td>Attended a Support Group</td>
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</tr>
<tr>
<td><strong>Mean</strong></td>
<td></td>
</tr>
<tr>
<td><strong>SD</strong></td>
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<tr>
<td>Age</td>
<td>56</td>
</tr>
<tr>
<td>Years of Education</td>
<td>14</td>
</tr>
</tbody>
</table>
Control group

A convenience sample of 13 breast cancer survivors who were referred to the investigator by area health care providers agreed to participate in, and completed this study. Descriptive statistics were also performed on this sample. As with the experimental sample, one subject did not provide information on lymph node involvement, and one additional subject did not provide information on type of surgery. The sample size for these two variables is 12 subjects. The median and mean age of subjects for this sample was 66 and 64 years respectively. The age range for this sample was also broad, with the youngest being 46 years of age and the oldest being 80 years of age. The mode for this sample was 66 years.

The subjects in this sample were all Caucasian and, like the experimental group, had an average of 14 years education. Among the 12 subjects who reported their surgical status, 42% had lumpectomy and 54% had mastectomy. Only 23% of this sample reported having participated in a support group, but 62% reported currently engaging in some form of exercise.

A chi-square test was performed to test the null hypothesis that there were no differences between the profiles of the experimental and the control subjects in this study. It is interesting that there were similarities between the subject groups with the exception of two areas (Table 1). First, there was a difference regarding the type of treatments. The experimental group subjects had been treated with chemotherapy more often than the control group (p=.037). In addition, the subjects in the experimental group had utilized a support group more than the control group. Both of these differences were statistically
significant (p=.000). An independent samples t-test found that the age difference between the two groups was not significant.

**Comparison of Subjects on Physical and Social Functioning and Vitality**

The first hypothesis of this study was to examine and compare the scores of the Return to Wellness study participants to a control group on the Physical Functioning (PF), Social Functioning (SF) and Vitality (VT) scales of the Medical Outcomes Study SF-36 Health Survey (Ware et al., 2000). The subjects were tested at three distinct points in time: prior to beginning the 10-week program, at midpoint, and at completion. The control subjects were tested at the time of informed consent, and again at five and ten weeks post consent. The means and standard deviations for the two subject groups are depicted in Table 2. The means for the experimental group were lower on all three scales at Time 1, indicating an initially lower level of functioning than the control subjects. At Time 3, the means of the experimental group were higher than the control group on all three scales, indicating a higher level of functioning. The null hypothesis of no significant differences in physical functioning, social functioning, and vitality before and after a 10 week period was tested using a repeated measures ANOVA with between-subjects analysis. The main effects of time and the interaction effect of group by time were significant on the social functioning and vitality scale, and approaching significance for the physical functioning scale (p=.06). The main effect of group was not significant on any of the scales. For all three scales the control group showed slight decline in scores over time, but not at a statistically significant level (Tables 3, 4, and 5).
Table 2

Descriptive Statistics by Group for PF, SF, and VT Scales of the SF-36 Health Survey

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>PF Time 1</td>
<td>Control</td>
<td>24.23</td>
<td>3.67</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>22.41</td>
<td>3.62</td>
<td>17</td>
</tr>
<tr>
<td>PF Time 2</td>
<td>Control</td>
<td>23.69</td>
<td>3.63</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>23.41</td>
<td>2.95</td>
<td>17</td>
</tr>
<tr>
<td>PF Time 3</td>
<td>Control</td>
<td>23.69</td>
<td>3.96</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>25.29</td>
<td>2.71</td>
<td>17</td>
</tr>
<tr>
<td>SF Time 1</td>
<td>Control</td>
<td>8.69</td>
<td>1.97</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>7.17</td>
<td>2.21</td>
<td>17</td>
</tr>
<tr>
<td>SF Time 2</td>
<td>Control</td>
<td>8.23</td>
<td>2.35</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>8.29</td>
<td>1.40</td>
<td>17</td>
</tr>
<tr>
<td>SF Time 3</td>
<td>Control</td>
<td>8.46</td>
<td>2.06</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>9.23</td>
<td>1.48</td>
<td>17</td>
</tr>
<tr>
<td>VT Time 1</td>
<td>Control</td>
<td>14.30</td>
<td>5.40</td>
<td>13</td>
</tr>
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<td></td>
<td>Experimental</td>
<td>11.58</td>
<td>3.24</td>
<td>17</td>
</tr>
<tr>
<td>VT Time 2</td>
<td>Control</td>
<td>13.69</td>
<td>4.95</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>12.82</td>
<td>3.87</td>
<td>17</td>
</tr>
<tr>
<td>VT Time 3</td>
<td>Control</td>
<td>14.07</td>
<td>3.96</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>15.23</td>
<td>3.64</td>
<td>17</td>
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</table>

Table 3

Physical Functioning: Main Effects and Interaction Effect

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Time</td>
<td>22.71</td>
<td>2</td>
<td>11.35</td>
<td>2.91</td>
<td>.062</td>
</tr>
<tr>
<td>Group</td>
<td>.608</td>
<td>1</td>
<td>.608</td>
<td>.022</td>
<td>.882</td>
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<tr>
<td>Time* Group</td>
<td>43.24</td>
<td>2</td>
<td>21.62</td>
<td>5.55</td>
<td>.006</td>
</tr>
</tbody>
</table>
Table 4

*Social Functioning: Main Effects and Interaction Effect*

<table>
<thead>
<tr>
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<th>p</th>
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</thead>
<tbody>
<tr>
<td>Time</td>
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<td>6.31</td>
<td>3.99</td>
<td>.024</td>
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<tr>
<td>Group</td>
<td>1.13</td>
<td>1</td>
<td>1.13</td>
<td>.143</td>
<td>.708</td>
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<tr>
<td>Time*Group</td>
<td>20.23</td>
<td>2</td>
<td>10.11</td>
<td>6.40</td>
<td>.003</td>
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</tbody>
</table>

Table 5

*Vitality: Main Effects and Interaction Effect*

<table>
<thead>
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<th>Source</th>
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<th>p</th>
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</thead>
<tbody>
<tr>
<td>Time</td>
<td>48.80</td>
<td>2</td>
<td>24.40</td>
<td>3.65</td>
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</tr>
<tr>
<td>Group</td>
<td>14.49</td>
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<td>.375</td>
<td>.545</td>
</tr>
<tr>
<td>Time*Group</td>
<td>55.42</td>
<td>2</td>
<td>27.71</td>
<td>4.15</td>
<td>.021</td>
</tr>
</tbody>
</table>

The within-subjects main effects of improvement over time were statistically significant for the experimental group on all three scales, but not significant for the control group on any of the three scales. The results by subject group are depicted in Tables 6, 7, and 8.
Table 6

*Physical Functioning: Main Effect of Time by Subject Groups*

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time –Control</td>
<td>2.51</td>
<td>2</td>
<td>1.25</td>
<td>.578</td>
<td>.569</td>
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<tr>
<td>Time- Experimental</td>
<td>72.82</td>
<td>2</td>
<td>36.41</td>
<td>7.02</td>
<td>.003</td>
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</table>

Table 7

*Social Functioning: Main Effect of Time by Subject Groups*

<table>
<thead>
<tr>
<th>Source</th>
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<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time –Control</td>
<td>1.38</td>
<td>2</td>
<td>.692</td>
<td>.543</td>
<td>.588</td>
</tr>
<tr>
<td>Time- Experimental</td>
<td>36.11</td>
<td>2</td>
<td>18.05</td>
<td>9.98</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Table 8

*Vitality: Main Effect of Time by Subject Groups*

<table>
<thead>
<tr>
<th>Source</th>
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<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time –Control</td>
<td>2.51</td>
<td>2</td>
<td>1.25</td>
<td>.284</td>
<td>.755</td>
</tr>
<tr>
<td>Time- Experimental</td>
<td>116.98</td>
<td>2</td>
<td>58.49</td>
<td>6.99</td>
<td>.003</td>
</tr>
</tbody>
</table>

_Comparison of Subjects on the Mishel Uncertainty in Illness Scale_

The second hypothesis of this study was to determine if there are differences over time in the level of uncertainty experienced by the subjects in the experimental group versus the control group subjects. The means and standard deviations for the two groups for this variable are depicted in Table 9. Scores on this instrument can range from 23 to
115 with higher scores indicating a greater level of uncertainty. The control group had a non-significant slight increase in scores over time. The repeated measures analysis of variance for the main effects of time, group, and the interaction effect of time by group appear in Table 10. The repeated measures ANOVA also demonstrated that the experimental group had a statistically significant decline in uncertainty scores over time, indicating that they were experiencing a lesser degree of uncertainty compared to Time 1. The results appear in Table 11.

Table 9

*Descriptive Statistics by Group for the Mishel Uncertainty in Illness Scale (MUIS-C)*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUIS Time 1</td>
<td>Control</td>
<td>45.00</td>
<td>20.51</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>53.41</td>
<td>10.91</td>
<td>17</td>
</tr>
<tr>
<td>MUIS Time 2</td>
<td>Control</td>
<td>47.69</td>
<td>20.25</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>50.52</td>
<td>12.13</td>
<td>17</td>
</tr>
<tr>
<td>MUIS Time 3</td>
<td>Control</td>
<td>46.76</td>
<td>18.82</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>43.64</td>
<td>14.19</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 10

*Uncertainty: Main Effects and Interaction Effect*

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>306.67</td>
<td>2</td>
<td>153.33</td>
<td>4.10</td>
<td>.022</td>
</tr>
<tr>
<td>Group</td>
<td>162.17</td>
<td>1</td>
<td>162.17</td>
<td>.231</td>
<td>.634</td>
</tr>
<tr>
<td>Time* Group</td>
<td>490.18</td>
<td>2</td>
<td>245.09</td>
<td>6.55</td>
<td>.003</td>
</tr>
</tbody>
</table>
Table 11

Uncertainty: Main Effect of Time by Subject Groups

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time –Control</td>
<td>48.66</td>
<td>2</td>
<td>24.33</td>
<td>.590</td>
<td>.562</td>
</tr>
<tr>
<td>Time- Experimental</td>
<td>855.80</td>
<td>2</td>
<td>427.90</td>
<td>12.40</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Comparison of Subjects of the Cancer Related Fatigue Distress Scale (CRFDS)

The final hypothesis of this study was to ascertain if there are significant differences in the amount of cancer related fatigue distress experienced by subjects in the Return to Wellness program versus a group of control subjects on the Cancer Related Fatigue Distress Scale. The means and standard deviations for the two groups on this measure are reported in Table 12. Scores on this instrument can range from 0-200, with higher scores indicating a greater level of distress from cancer related fatigue. At Time 1, the experimental subjects had higher mean scores than the control group. Repeated measures analysis of variance for the main effects of time and group and the interaction effect of time by group results appear in Table 13. The within-subjects effects demonstrated a statistically significant decline in scores for the experimental subjects indicating that they were experiencing less distress from cancer related fatigue over time. The analysis of within-subjects effects for the control group yielded no significant change in scores. These results appear in Table 14.
Table 12

*Descriptive Statistics by Group for the Cancer Related Fatigue Distress Scale*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRFDS Time 1</td>
<td>Control</td>
<td>67.76</td>
<td>59.37</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>89.11</td>
<td>46.13</td>
<td>17</td>
</tr>
<tr>
<td>CRFDS Time 2</td>
<td>Control</td>
<td>67.15</td>
<td>61.30</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>73.05</td>
<td>43.84</td>
<td>17</td>
</tr>
<tr>
<td>CRFDS Time 3</td>
<td>Control</td>
<td>66.38</td>
<td>60.78</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Experimental</td>
<td>67.47</td>
<td>52.47</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 13

*Cancer Related Fatigue Distress: Main Effects and Interaction Effect*

<table>
<thead>
<tr>
<th>Source</th>
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<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>2928.97</td>
<td>2</td>
<td>1464.48</td>
<td>3.82</td>
<td>.028</td>
</tr>
<tr>
<td>Group</td>
<td>1337.60</td>
<td>1</td>
<td>1337.60</td>
<td>.171</td>
<td>.682</td>
</tr>
<tr>
<td>Time* Group</td>
<td>2389.51</td>
<td>2</td>
<td>1194.75</td>
<td>3.12</td>
<td>.052</td>
</tr>
</tbody>
</table>

Table 14

*Cancer Related Fatigue Distress: Main Effect of Time by Subject Groups*

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time –Control</td>
<td>12.51</td>
<td>2</td>
<td>6.25</td>
<td>.035</td>
<td>.966</td>
</tr>
<tr>
<td>Time- Experimental</td>
<td>6120.35</td>
<td>2</td>
<td>3060.17</td>
<td>5.70</td>
<td>.008</td>
</tr>
</tbody>
</table>
Chapter Five

Discussion

The focus of this study was to determine the effects of a structured 10-week combined recovery program for breast cancer survivors called Return to Wellness. Chapter five discusses findings, conclusions, study limitations, and discusses implications for nursing practice and education. It also discusses recommendations for future research.

The hypotheses for this study were as follows:

Women with breast cancer who complete the Return to Wellness program will:

1. report significantly improved physical functioning, social functioning and vitality compared to a control group as reported on PF, SF and VT scales of the SF-36.
2. have significantly lower scores on the Mishel Uncertainty in Illness Scale (MUIS) compared to a control group.
3. report significantly less distress from fatigue on the Cancer Related Fatigue Distress Scale (CRFDS) compared to a control group.

*Physical and Social Functioning and Vitality*

The mean pre-test (Time 1) scores of the experimental subjects were lower than those of the control group on all three of these scales of the SF-36, indicating a lower level of functioning. At completion of the Return to Wellness program, the scores of the subjects had improved significantly over time, whereas there were no significant differences in the control group on any of the three measures. Both groups of subjects
reported participating in exercise prior to beginning the study (65% of the experimental group and 62% of the control group). This was not a statistically significant difference. Although there was improvement in the scores of the experimental subjects, it is not known if they, or the control group, were exercising according to the CDC recommendations of 30 minutes of moderate activity five times per week or 20 minutes or more of vigorous activity three times per week (Department of Health and Human Services Centers for Disease Control and Prevention/American College of Sports Medicine, 2005). The Return to Wellness program does not have written goals and objectives. In developing and articulating goals and objectives for the program, it may be beneficial to use the CDC guidelines or to write objectives to a target metabolic equivalent task (MET) for each session. One MET is equivalent to sitting quietly, while average-paced walking equals 3 MET (Holmes, 2005). It may also be helpful to introduce various types of exercise other than yoga, free weights, or resistance bands, as the literature demonstrates that patients are more likely to exercise when the exercise is matched to their preference (Courneya, 2003).

**Uncertainty in Illness**

The mean scores of the experimental subjects on the first two measures of the Mishel Uncertainty in Illness Scale were higher than those of the control group, indicating that the experimental group was experiencing a higher level of uncertainty. Anecdotally, one subject in the experimental group commented to the researcher just before the midpoint assessment that she thought the midpoint survey values might be worse because she felt that as a group, they were just delving into psychological issues that could not be previously addressed due to the more pressing needs of physical
treatment. However, the mean scores of the midpoint assessment were slightly lower, and the level of uncertainty across all three measurement points continued to decline. This finding was statistically significant. Meanwhile, there were no statistically significant changes across time in the scores of the control group. The changes in the scores of the experimental group support Mishel’s Uncertainty in Illness Theory that purports that, according to Mishel, (1990) education, credible authority and social support are effective mediators of uncertainty. The Return to Wellness program provided support and/or education at every session, but what is not known is how much social support or education was received outside the program. The demographic form completed by the Return to Wellness participants, as well as the information sheet completed by the control group did not inquire about marital or significant other status. Prior to beginning the Return to Wellness program, 100% of the experimental group reported having attended a support group, whereas only 23% of the control subjects reported visiting a support group, which was a statistically significant finding.

*Cancer Related Fatigue Distress*

The experimental group had higher mean scores on the Cancer Fatigue Related Distress Scale than the control subjects at all three time points, indicating a greater amount of distress and suffering associated with fatigue (Holley, 2000b) This could possibly be attributed to the fact that the experimental group had significantly more chemotherapy than the control group, and this treatment is associated with a higher incidence and degree of fatigue (Donovan et al., 2004; Woo et al., 1998). Even so, the experimental group of Return to Wellness participants had a statistically significant decrease over time in their scores on the CRFDS. The control group did not have a
statistically significant change in scores over time on this instrument. The Return to Wellness program includes a lecture on fatigue management and energy conservation. The program also includes twice-weekly exercise sessions. Exercise is known to be a mediator of fatigue (Barsevick et al., 2002).

Limitations of the study

Sample

In order for this study to have power to detect a medium effect size, the intended sample for each group in this study was 45 subjects. However, lack of participants in the Return to Wellness program and lack of referrals of post-treatment survivors by area health care providers contributed to low enrollment in the study. In the end, funding was cut for the Return to Wellness program so that the program was not able to continue as often or with the same curriculum.

Another sample limitation of this study is that these two convenience samples consisted primarily of Caucasian women. The experimental group was 94% Caucasian and 6% Hispanic. The control group was 100% Caucasian. There were no African American women recruited into the study. The group demographics do not adequately represent the community in which the Return to Wellness program is held, nor do they represent the ethnic distribution of women with breast cancer (American Cancer Society, 2004). Despite efforts on the part of The Wellness Community to reach out to the African American and Hispanic communities, and in particular to attempt to recruit African American and Hispanic breast cancer survivors into the Return to Wellness program, these minority groups of survivors are not being reached, nor studied for the effects of a recovery program. There are two possible explanations. The first is location.
The Wellness Community and the satellite center of the partner hospital are located a fairly good distance from the African American and Hispanic communities, and not easily accessible via public transportation. The second possible reason is that statistics bear out the fact that minority women are often diagnosed with breast cancer at a later stage than Caucasian women (American Cancer Society, 2004). Women who are diagnosed at a later stage may have poorer performance status and therefore may not be able to travel to or participate in a recovery program.

Method

Because this was not a randomized control trial, there is a degree of bias in that the subjects self-selected to participate in the study. It is not known if subjects responded in a socially desirable way on the surveys. Several subjects in the control group seemed determined to reveal their identity by sending signed notes and cards with their surveys, adding their return address to the pre-addressed return address, and putting return address stickers on every page of every survey. All identifying data was removed by the investigator, but even with such maneuvers, it is impossible to know that the surveys were actually completed by the subject to whom they were addressed. Another limitation in method is that the Return to Wellness program is a multifaceted intervention, and it is difficult to attribute cause and effect to one single intervention in order to determine what had the greatest effect.

Generalizability

Although it is tempting to generalize the findings of this study in order to move toward evidence-based recommendations for care, these findings are what they are: a representation of the small number of specific survivors who agreed to participate in this
study. It would be inappropriate to generalize these finding to other recovery or exercise programs, or to groups of cancer patients or post-treatment survivors. These results definitely cannot be applied to populations that were not represented in the subject groups. It is possible that women who chose not to participate in the study were systematically different from those who did participate. This also limits generalizability. Further studies are recommended across various geographic areas and ethnic populations to test for social and cultural sensitivity and preference in addition to effect.

**Recommendations for Future Research**

Nurses should continue to investigate the effects of post-treatment recovery programs for breast cancer survivors. They should be involved in the design of these programs and see that goals and objectives are outcome and evidence-based. Future research studies should examine barriers to participation in post-recovery programs, and test interventions that motivate and sustain survivors to participate. Nursing should also investigate whether the ideal locale for a recovery program is home-based or in a structured group, and how long programs should be and what they need to include in order to be effective. Nursing should conduct long term longitudinal studies of survivors who sustain the CDC recommendations for physical activity to examine effect on recurrence and survival. We should also investigate culturally sensitive issues surrounding participation in recovery programs in order to bring the same standard of care to minority and underserved populations.
Conclusion

All three of the hypotheses in this study are confirmed. Based on the findings of this study, a formal recovery program should be considered for breast cancer survivors who have completed treatment. The Return to Wellness program was an effective mediator of uncertainty and cancer related fatigue distress for the group of subjects who completed the program. The subjects also realized improved physical and social functioning, and an increased level of vitality versus a similar group of control subjects. Future research is recommended to test for effects in more diverse populations, and in a randomized control trial setting in order to support formalized recovery programs as evidence-based practice recommendations.
References


Segal, R., Evans, W., Johnson, D., Smith, J., Colletta, S., Gayton, J., et al. (2001). Structured exercise improves physical functioning in women with stages I and II


Appendix A: Consent to Participate in the Return to Wellness Program
RETURN TO WELLNESS
Waiver and Physician Release Agreement

I, the **UNDERSIGNED**, fully understand and agree to the following:

1. The Wellness Community--Southwest Florida, through its *Return to Wellness* Program, will provide a ten-week program for women who have recently completed treatment for breast cancer. This program will meet for two hours, twice each week. Of the four hours per week, there will be one hour of yoga, one hour of strength training (using resistance bands), one hour of support group, and one hour of educational programming on nutrition and other breast cancer-related topics. The purpose of this program is to encourage breast cancer survivors to optimize their recovery by improving their physical health, knowledge of healthy living practices, and social/emotional health.

2. Participation in any exercise program, such as the yoga and strength training programs offered in *Return to Wellness*, may result in foreseeable or unforeseeable injury or illness, including, but not limited to, bodily injury, death, disease, strains, fractures, herniations, ruptures, tears, partial or total paralysis, heart attacks, stroke, infection, allergic reaction, and other ailments that could cause serious disability.

3. Prior to your participation in *Return to Wellness*, The Wellness Community--Southwest Florida, requires you to consult with your physician regarding your participation in the exercise programs, as consistent with your health care regimen and appropriate to your medical condition. Your doctor also hereby acknowledges that
your active cancer treatment was completed at least three weeks, but no more than two years, ago.

4. By affixing your signature to this document in the space provided below, you, and all your personal representatives, assigns, heirs, spouse and next-of-kin, agree to release, waive, discharge and hold harmless The Wellness Community–Southwest Florida and Sarasota Memorial Health Care System and its respective employees, shareholders, officers, agents, independent contractors, volunteers and donors from any and all claims, actions, demands, liabilities, expenses (including attorneys’ fee) and losses arising from bodily injury or illness as described above, including, but not limited to, wrongful death, loss of services, loss of consortium, and all other damages that may arise out of participation in the Return to Wellness program as described above.

THE UNDERSIGNED HAS READ AND UNDERSTOOD THE WAIVER AND RELEASE AGREEMENT.

Signature:______________________ ______________________ _________
Return to Wellness Participant Print Name                                       Date
(the UNDERSIGNED)

___________________________ __________________________ ___________
Physician Signature  Print Name   Date
Appendix B: Participant Personal History Form
Measuring the Effects of Rehabilitation Program for Breast Cancer Survivors
Principal Investigator: Keri Hockett ARNP MSN AOCN

Participant Information

Name________________________________________Date of Birth______________

Highest grade completed________________________Ethnicity__________________

Type of cancer__________________________________________________________

Lymph node involvement _____ local _____ regional _____ metastatic _____ not sure
Number of lymph nodes involved__________________________ _____ not sure

Type of surgery performed and date _________________________________________

When did you complete your treatment? (do not consider hormone therapy such as tamoxifen or Arimidex, Femara, etc) ______________________________________________________

Therapies used to treat your breast cancer ____surgery ____chemotherapy
____radiation ____hormone therapy ____biotherapy ____other___________________

Have you experienced lymphedema since your surgery? ___yes ___no

Do you currently participate in any form of exercise? ___yes ___no

If yes, what type of exercise do you participate in?________________________________

How often do you participate in the above exercises? _____________________________

Have you ever attended a cancer support group? ___yes ___no
Appendix C: Sample Return to Wellness Schedule
## Return To Wellness – Southwest Florida

Winter Course Schedule - Blake Medical Center

<table>
<thead>
<tr>
<th>Week 1 – January 12th &amp; 15th</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monday 9:30 – 11:45</strong></td>
</tr>
<tr>
<td>Orientation/Introductions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 2 – January 19th &amp; 22nd</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monday</strong></td>
</tr>
<tr>
<td>9:30 – 10:30 Yoga</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 3 – January 26th &amp; January 29th</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monday</strong></td>
</tr>
<tr>
<td>9:30 – 10:30 Yoga</td>
</tr>
<tr>
<td>10:45 – 11:45 “Understanding Our Feelings: How To Manage Emotional Dis-ease” M.R. Lembright, LMHC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 4 – February 2nd &amp; February 5th</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Monday</strong></td>
</tr>
<tr>
<td>9:30 – 10:30 Yoga</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
</tr>
</tbody>
</table>
### Return To Wellness – Southwest Florida

#### Week 5 – February 9<sup>th</sup> & February 12<sup>th</sup>

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 10:30 Support Group</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
<td>10:45 – 11:45 Conditioning &amp; Range of Motion</td>
</tr>
</tbody>
</table>

#### Week 6 – February 16<sup>th</sup> & February 19<sup>th</sup>

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 10:30 Support Group</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
<td>10:45 – 11:45 Conditioning &amp; Range of Motion</td>
</tr>
</tbody>
</table>

#### Week 7 – February 23<sup>rd</sup> & February 26<sup>th</sup>

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 10:30 Support Group</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
<td>10:45 – 11:45 Conditioning &amp; Range of Motion</td>
</tr>
</tbody>
</table>

#### Week 8 – March 1<sup>st</sup> & March 4<sup>th</sup>

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 10:30 Support Group</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
<td>10:45 – 11:45 Conditioning &amp; Range of Motion</td>
</tr>
</tbody>
</table>
### Week 9 – March 8\(^{th}\) – March 11\(^{th}\)

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 10:30 Support Group</td>
</tr>
<tr>
<td>10:45 – 11:45 Education</td>
<td>10:45 – 11:45 Conditioning &amp; Range of Motion</td>
</tr>
</tbody>
</table>

### Week 10 – March 15\(^{th}\) – March 18\(^{th}\)

<table>
<thead>
<tr>
<th>Monday</th>
<th>Thursday</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 10:30 Yoga</td>
<td>9:30 – 11:45 Physical Assessment &amp; Home Exercise</td>
</tr>
<tr>
<td>10:45 – 11:45 Support Group</td>
<td>Program Completion &amp; Graduation</td>
</tr>
</tbody>
</table>
Appendix D: Instruments
CANCER RELATED FATIGUE DISTRESS SCALE (CRFDS)
Sandra Holley, PhD, ARNP, AOCN

INSTRUCTIONS:

Below and on the next 3 pages are a list of problems people sometimes have because of their cancer related fatigue. Please read each one carefully. Please circle the number that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS, INCLUDING TODAY. Circle only one number for each problem and do not skip any items. If you change your mind, erase your first mark carefully. Read the example before beginning, and if you have any questions please ask then now.

Please Complete All 20 Items and the 4 additional items on the last page

The fatigue or tiredness I am having causes me distress because it:

1. makes it difficult for me to concentrate.

   How much distress does this cause you?

   |   0 |   1 |   2 |   3 |   4 |   5 |   6 |   7 |   8 |   9 |  10 |
   |-----------------------------------------------|
   | No distress | Severe distress |

2. makes me feel that I must accept more help from others.

   How much distress does this cause you?

   |   0 |   1 |   2 |   3 |   4 |   5 |   6 |   7 |   8 |   9 |  10 |
   |-----------------------------------------------|
   | No distress | Severe distress |

3. makes me feel that I am more than just tired.

   How much distress does this cause you?

   |   0 |   1 |   2 |   3 |   4 |   5 |   6 |   7 |   8 |   9 |  10 |
   |-----------------------------------------------|
   | No distress | Severe distress |

4. makes me feel frustrated when I can’t do what I used to do.

   How much distress does this cause you?

   |   0 |   1 |   2 |   3 |   4 |   5 |   6 |   7 |   8 |   9 |  10 |
   |-----------------------------------------------|
   | No distress | Severe distress |
The fatigue or tiredness I am having causes me distress because it:

5. makes my body feel as though it doesn’t want to function.
   
   How much distress does this cause you?
   
<table>
<thead>
<tr>
<th>No distress</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. makes it difficult for me to form whole thoughts.
   
   How much distress does this cause you?
   
<table>
<thead>
<tr>
<th>No distress</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. makes me feel like my physical abilities are being worn away.
   
   How much distress does this cause you?
   
<table>
<thead>
<tr>
<th>No distress</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. makes me feel that I am still tired after sleeping.
   
   How much distress does this cause you?
   
<table>
<thead>
<tr>
<th>No distress</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. makes me feel guilty when I can’t do the things that are my usual jobs to do.
   
   How much distress does this cause you?
   
<table>
<thead>
<tr>
<th>No distress</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. makes me too tired to eat.
    
    How much distress does this cause you?
    
    | No distress | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
    |-------------|---|---|---|---|---|---|---|---|---|----|
    | Severe distress |   |   |   |   |   |   |   |   |   |    |

11. makes me limit my family and social activities.
    
    How much distress does this cause you?
    
    | No distress | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
    |-------------|---|---|---|---|---|---|---|---|---|----|
    | Severe distress |   |   |   |   |   |   |   |   |   |    |
The fatigue or tiredness I am having causes me distress because it:

12. makes me feel tired more quickly than typical fatigue.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

13. makes me feel uncertain about my future.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

14. makes me feel totally exhausted.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

15. makes me feel like I am a different person.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

16. makes me stay at home more.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

17. makes me feel a loss of control over my life.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

18. makes it difficult for me to remember things.

   How much distress does this cause you?
   
   0  1  2  3  4  5  6  7  8  9  10

   No distress

65
The fatigue or tiredness I am having causes me distress because it:

19. makes me feel as if I have no energy.

   How much distress does this cause you?

   0  1  2  3  4  5  6  7  8  9  10
   No distress                                     Severe distress

20. makes me feel like I am losing interest in things.

   How much distress does this cause you?

   0  1  2  3  4  5  6  7  8  9  10
   No distress                                     Severe distress

Please circle the number that most describes your fatigue.

<table>
<thead>
<tr>
<th>Fatigue level now</th>
<th>No Fatigue</th>
<th>Severe Fatigue</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Worst fatigue level</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Since having cancer</th>
<th>Usual fatigue level</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

Please circle the one number below that best describes your situation now

**KARNOFSKY PERFORMANCE SCALE (Wingard et al., 1991)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Normal; no complaints; no evidence of disease</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some sign or symptoms of disease</td>
</tr>
<tr>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or do active work</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance, but is able to care for most personal needs</td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care</td>
</tr>
<tr>
<td>40</td>
<td>Disabled; requires special care and assistance</td>
</tr>
</tbody>
</table>
MISHEL UNCERTAINTY IN ILLNESS SCALE- COMMUNITY FORM

INSTRUCTIONS:

Please read each statement. Take your time and think about what each statement says. Then place an “X” under the column that most closely measures how you are feeling TODAY. If you agree with a statement, then you would mark under either “Strongly Agree” or “Agree”. If you disagree with a statement, then mark under either “Strongly Disagree” or “Disagree”. If you are undecided about how you feel, then mark under “Undecided” for that statement. Please respond to every statement.

1. I don’t know what is wrong with me.

   Strongly Agree (5)   Agree (4)   Undecided (3)   Disagree (2)   Strongly Disagree (1)

   _______   _______   _______   _______   _______

2. I have a lot of questions without answers.

   Strongly Agree (5)   Agree (4)   Undecided (3)   Disagree (2)   Strongly Disagree (1)

   _______   _______   _______   _______   _______

3. I am unsure if my illness is getting better or worse

   Strongly Agree (5)   Agree (4)   Undecided (3)   Disagree (2)   Strongly Disagree (1)

   _______   _______   _______   _______   _______

4. It is unclear how bad my pain will be.

   Strongly Agree (5)   Agree (4)   Undecided (3)   Disagree (2)   Strongly Disagree (1)

   _______   _______   _______   _______   _______

©Merle Mishel, Revised 1990
5. The explanations they give about my condition seem hazy to me

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. The purpose of each treatment is clear to me.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. My symptoms continue to change unpredictably.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. I understand everything explained to me.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. The doctors say things to me that could have many meanings.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. My treatment is too complex to figure out.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
11. It is difficult to know if the treatments or medications I am getting are helping

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

12. Because of the unpredictability of my illness, I cannot plan for the future.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

13. The course of my illness keeps changing. I have good and bad days.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

14. I have been given many differing opinions about what is wrong with me.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

15. It is not clear what is going to happen to me.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

16. The results of my tests are inconsistent.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>
17. The effectiveness of the treatment is undetermined.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

18. Because of the treatment, what I can do and cannot do keeps changing.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

19. I’m certain they will not find anything else wrong with me.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

20. The treatment I am receiving has a known probability of success.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

21. They have not given me a specific diagnosis.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>

22. The seriousness of my illness has been determined.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
</tr>
</tbody>
</table>
23. The doctors and nurses use everyday language so I can understand what they are saying.

<table>
<thead>
<tr>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Undecided (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an □ in the one box that best describes your answer.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now?

<table>
<thead>
<tr>
<th>Much better now than one year ago</th>
<th>Somewhat better now than one year ago</th>
<th>About the same as one year ago</th>
<th>Somewhat worse now than one year ago</th>
<th>Much worse now than one year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>
3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifting or carrying groceries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climbing several flights of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climbing one flight of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bending, kneeling, or stooping</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking more than a mile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking several blocks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking one block</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bathing or dressing yourself</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

a. Cut down on the amount of time you spent on work or other activities ........................................................................................................................................................................... 1 2

b. Accomplished less than you would like ........................................................................................................................................................................................................................................... 1 2

c. Were limited in the kind of work or other activities ........................................................................................................................................................................................................................................................................................................... 1 2

d. Had difficulty performing the work or other activities (for example, it took extra effort) .................................................................................................................................................................................................................................................................................. 1 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

a. Cut down on the amount of time you spent on work or other activities ........................................................................................................................................................................................................................................................................................................... 1 2

b. Accomplished less than you would like ........................................................................................................................................................................................................................................................................................................... 1 2

c. Did work or other activities less carefully than usual .......................................................................................................................................................................................................................................................................................................................................................... 1 2
6. **During the past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. **How much bodily pain have you had during the past 4 weeks?**

<table>
<thead>
<tr>
<th>None</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. **During the past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>


10. **During the past 4 weeks**, how much of the time has your **physical health** or **emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5

11. **How TRUE or FALSE is each** of the following statements for you?

<table>
<thead>
<tr>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
</table>

- I seem to get sick a little easier than other people ........................................... ☐ 1  ........... ☐ 2  ........... ☐ 3  ........... ☐ 4  ........... ☐ 5
- I am as healthy as anybody I know ............................................................................ ☐ 1  ........... ☐ 2  ........... ☐ 3  ........... ☐ 4  ........... ☐ 5
- I expect my health to get worse .................................................................................. ☐ 1  ........... ☐ 2  ........... ☐ 3  ........... ☐ 4  ........... ☐ 5
- My health is excellent .................................................................................................... ☐ 1  ........... ☐ 2  ........... ☐ 3  ........... ☐ 4  ........... ☐ 5

Thank you for completing these questions!
Appendix E: Institutional Review Board Approval
April 6, 2004

Keri Hockett, MSN
5833 Carriage Drive
Sarasota, FL 34243

Dear Ms. Hockett:

Your new protocol (IRB #102406) entitled, "Measuring the Effects of a Rehabilitation Program for Breast Cancer Survivors" including the informed consent form has been reviewed under expedited review category seven (7). Having made any required revisions, the approval period for your protocol is shown on the stamp below. This information shall be presented to the Institutional Review Board-02 at its next convened meeting on May 21, 2004.

You should take special note of the following:

- Unless the requirement has been waived by the IRB, documentation of informed consent/assent must be obtained on copies of the attached stamped informed consent/assent document. Please note the form is valid only during the period stamped on the informed consent/assent document.
- Approval is for up to a twelve-month period, after date of initial review. A Research Progress Report to request renewed approval must be submitted to this office by the submission deadline in the eleventh month of this approval period. A final report must be submitted if the study was never initiated, or if the sponsor closed the study.
- Any changes in the above referenced study may not be initiated without IRB approval except in the event of a life-threatening situation where there has not been sufficient time to obtain IRB approval.
- All changes in the protocol must be reported to the IRB.
- If there are any adverse events, the Chairperson of the IRB must be notified immediately in writing.
- Please note, Research investigators are required to keep all research related materials, including all IRB correspondence for no less than three (3) years. If at the end of 3 years, the data is no longer needed it should be destroyed. However, if data are kept after 3 years of study completion, please report to the IRB how you will keep data confidential.

Based on the new HIPAA Privacy Rule, if the study involves generating, collecting, using, or disclosing "protected health information" the subject must be given an appropriately approved Authorization form prior to enrolling them into your research study. If the study involves review of medical charts only, please ensure that you have a Waiver of HIPAA Authorization granted by the Privacy Board, prior to commencing the study.

If you have any questions regarding this matter, please do not hesitate to call Christy Stephens at (813) 974-3218 or myself at (813) 974-9343.

Sincerely,

Paul G. Stites, J.D., Ph.D.
Chairperson, IRB-02

PGS: cas
pc: Dr. McMillan

DIVISION OF RESEARCH COMPLIANCE
University of South Florida • 12921 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4704
(813) 974-5618 • FAX (813) 974-5615

IRB Approval
FWA 0001060

IRB Numbers: 102406

From 4-6-04
Thru 4-5-05

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Appendix F: Informed Consent
Informed Consent and Authorization To Participate In A Research Study

Title: Measuring the Effects of a Rehabilitation Program for Breast Cancer Survivors

Principal Investigator: Keri Hockett ARNP, MSN, AOCN

Subject Name:

INTRODUCTION

You are asked to participate in a research study conducted in Sarasota Florida by Keri Hockett ARNP, MSN, AOCN for the University of South Florida. You have been asked to participate in this study because you are a breast cancer survivor who has completed treatment. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether or not to participate.

For you to be able to decide to take part in this study, you should be informed about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form describes the purpose, procedures and possible benefits and risks of the study.

PURPOSE OF THE STUDY

This study will examine the effects of a breast cancer rehabilitation program called Return to Wellness on breast cancer survivors who have completed treatment in the last three weeks to two years.

NUMBER OF SUBJECTS INCLUDED IN THE STUDY

Approximately 120 subjects may take part in this study. Approximately 60 subjects will be recruited from the Return to Wellness program and approximately 60 subjects will be recruited who are not participating in the Return to Wellness program. You may be able to join if you qualify for this study. The complete study could last up to 10 weeks and requires no study visits.

DESCRIPTION OF PROCEDURES

There are three health surveys for the study
Survey 1) The Medical Outcomes Survey Short Form- 36, or SF-36.
Survey 2) The Cancer Related Fatigue Distress Scale (CRFDS)
Survey 3) The Mishel Uncertainty in Illness Scale- Community Form (MUIS-C)

You will complete all three health surveys on three separate occasions. If you are participating in the Return to Wellness program, you will complete the three surveys prior to beginning the program, again at the beginning of the 6th session, and finally, one more time at the completion of session 10.

If you are not participating in the Return to Wellness program, the surveys will be mailed to you at the address you provide, and you will take the first set of surveys at a time most convenient to you. The second survey time will be five weeks after the first surveys are completed, and the last set of surveys will be completed five weeks after the second set. You will be given pre-addressed, postage-paid envelopes to return your surveys. You may be sent occasional follow-up letters reminding you to complete and return your surveys.

You will also be asked to complete a basic information form. It will ask you about personal characteristics such as age and education; lifestyle factors such as exercise, and a brief medical history. You will only be asked to provide this information one time, at the time that the first surveys are given.

Over the 10 week study period, we estimate the total estimated time it will take you to complete all three surveys at three separate intervals will be 1.5 hours.

RISKS AND DISCOMFORTS ASSOCIATED WITH THIS STUDY

We do not anticipate any risks and discomforts to you if you complete the study. You can choose not to answer any question for any reason.

POTENTIAL BENEFITS

There may be no direct benefit to you, however the knowledge gained could help breast cancer survivors in the future.

ALTERNATIVE PROCEDURES

- There are no alternative test procedures

NEW FINDINGS

To let you know the study findings, we will send a report to you. If you would like an abstract of the results sent to you, please mark “yes” on the enclosed form and fill in your name and address. Mail this form back in the separate postage

IRB #: 102404
Approved From 4-6-04
Approved Thru 4-5-05
The purpose of the IRB is to review the risk and benefits for the safety of subjects participating in this research study. If you have any questions regarding your rights as a research subject, your participation in the study and/or concerns about the study, or if you feel undue pressure to enroll in this study or to continue to participate in this study, you should contact the Division of Research Compliance of the University of South Florida at 813-974-5638.

CONFIDENTIALITY

Your name and what you write for this study will be kept private to the extent allowed by law. You will see that your surveys do not ask your name or for any other way to identify you. But, you will see that they are stamped with a unique study identification number in the top margin. That number matches to your name on a list. We will keep that list only to track who has and has not responded. That list will be stored in a locked file in the office of Keri Hockett ARNP, MSN, AOCN, and her immediate supervisor will maintain the key to the file. The completed surveys and personal data forms will be stored in a separate locked file and only the principle investigator and her supervisory committee will be allowed to look at them. After we finish the study, approximately one year from now, we will destroy the list matching the names and study identification numbers. This will break any link to the names of persons who completed the study. Your name or other facts that might point to you will not appear when we present this study or publish its results. Data will be reported only as grouped data. All study information that is shared with persons outside of the University of South Florida will have your name and other identifying characteristics removed, so that your identity will not be revealed. We will not share your personally identifiable surveys or personal data.

Your privacy and research records will be kept confidential to the extent of the law. Authorized research personnel, employees of the Department of Health and Human Services, the USF Institutional Review Board and its staff, and other individuals, acting on behalf of USF, may inspect the records from this research project.

VOLUNTARY PARTICIPATION WITHDRAWAL

Your participation in this study is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled. We will not contact you further about any
Dear Patient:

My name is Keri Hockett ARNP, MSN, AOCN and I am a doctoral candidate at the University of South Florida College of Nursing. I am conducting a research study on the effects of a rehabilitation program on breast cancer survivors who have completed treatment. I am looking for the effects of a specific program called Return to Wellness on patient self-report surveys of physical functioning, social role functioning, distress from fatigue, and uncertainty.

I am asking for volunteers to take a series of health related surveys over the course of a 10 week period. I will be seeking volunteers from the actual Return to Wellness program as well as breast cancer survivors who are not participating in the Return to Wellness program.

People who are eligible to participate in this study are women who have had a breast cancer diagnosis and have completed treatment in the last three weeks to two years, and are over age 18, not pregnant, and who currently have no active cancer.

The information gained from this study may help us understand the role of rehabilitation programs for cancer survivors. If you are interested in participating in this research study, an informed consent process explaining the risks and benefits of the study will occur. This will allow you opportunity to ask questions and to decide if you would like participate in the study.

To learn more about this study, or to inquire about participation, please contact Keri Hockett, ARNP, MSN, AOCN at 941-917-7425

Thank you,
Sincerely

Keri Hockett
Doctoral Candidate
University of South Florida
College of Nursing
About the Author

Keri Ann Cassidy Hockett received a Bachelor of Science in Nursing Degree from Villanova University, Villanova, PA in 1980 and a Master of Science in Nursing Degree from the University of South Florida in Tampa, FL in 1993. She has worked for the past 25 years at Sarasota Memorial Health Care System in the positions of staff nurse, clinical nurse specialist, and nurse practitioner in adult medical oncology. She has most recently been in the position of clinical nurse researcher, while working towards her Ph.D. degree in nursing at the University of South Florida.

Ms. Hockett was appointed by Florida Governor Jeb Bush to a four year term on the Florida Board of Nursing, completing her term in March 2005. Throughout her term, she served as chair of the ARNP committee, working on key legislative matters that affect advanced nursing practice. She is an active member of the Oncology Nursing Society (ONS) and has presented from the podium several times at the ONS National Congress. She has authored publications in the *Clinical Journal of Oncology Nursing* and the American Cancer Society textbook *A Cancer Resource Book for Nurses 8th Edition.*